

**APPLICATION 10/634,869** 

## **Information Disclosure Statement**

Copies of documents presented for consideration are listed on a separate form, but also are noted below with "extras" -- commentary and directions - to direct the reviewer. These documents refer to three epidemiology (human) data sets: [A] the Taiwan data set, part of which the EPA regulators relied on in lowering the arsenic in drinking water standard from 50 to  $10 \mu g/L$  (or parts per billion [ppb]); [B] the Millard, Utah data set that EPA scientists collected and published on, but EPA regulators ignored; and [C] the Cuzak data set of British patients treated medicinally for non cancer ills with arsenic.

#### A.

- 1. Kayajanian, G. "Arsenic, cancer and thoughtless policy" (2003). <u>Ecotoxicology and Environmental Science</u> 55: 139-142. This paper examines broad cancer groupings in all three data sets.
- 2. Pages 308-309 [Table A-10-1] NRC (NAS) 1999 Arsenic in Drinking Water Report. National Academy Press. These two pages contain the actual data EPA employed to justify lowering the arsenic standard; Kayajanian also relied on this table to contradict the EPA claims and, in part, to make his patent claims.
- 3. Morales, KH, Ryan, L et al., "Risk of Internal Cancers from Arsenic in Drinking Water" (2000). Environmental Health Perspectives 108(7): 655-661. This paper draws the EPA conclusion that lowering the arsenic level always lowers the bladder cancer mortality. Note particularly in Table 5 the Cancer and PYR (person-years) entries associated with exposure categories 0-50 and 50-100. The cancer rate increases in 0-50 compared to 50-100, which Morales, Ryan fail to note, even as they validate the kind of comparison Kayajanian makes using exposure groupings [(10-32) and (42-60)], which are more relevant to the EPA regulatory question: Should EPA keep the arsenic-in-drinking-water standard at 50 ppb or lower it?

### B.

- 4. Cover sheet (identity of sender deleted), two tables, five-page 2000 EPA Report ["A Re-Analysis of Arsenic-Related Bladder and Lung Cancer Mortality in Millard County, Utah"] and 55-page data set on the Millard, Utah population published on by Lewis, Southwick et al. in 1999.
- 5. Manuscript: Kayajanian, G. "J-shaped Disease Response to Arsenic Levels in Utah Drinking Water" based on the 55-page Millard, Utah set, drafted prior to this patent filing.

#### C.

6. Cuzick, J., Evans, S. et al. "Medicinal Arsenic and Internal Malignancies" (1982). British Journal Cancer 45: 904-910. See Table III.

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known Application Number Filing Date First Named Inventor Art Unit **Examiner Name** JAMES

(Use as many sheets as necessary) Attorney Docket Number OND Sheet

			U. S. PATENT D	OCUMENTS	.00
Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
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INFORMATION DISCLOSURE

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Application Number

Io/634,869

Filling Date

First Named Inventor

Art Unit

Complete if Known

Io/634,869

FIRST Named Inventor

KAYAJANIAN G

(Use as many sheets as necessary)

STATEMENT BY APPLICANT

Sheet 4 of

Examiner Name

Tames D. Ander

Attorney Docket Number

Examiner Initials.

| Cite | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the litem (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

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